

## 1. DESCRIPTION OF OECD WORK ON INVESTIGATION OF HIGH PRODUCTION VOLUME CHEMICALS\*

### *Summary*

Through a 1990 OECD Council Decision [C(90)163(Final)] (see Annex 1 to this Manual) Member countries have decided to undertake the investigation of high production volume (HPV) chemicals in a co-operative way. These HPV chemicals include all chemicals reported to be produced or imported at levels greater than 1,000 tonnes per year in at least one Member country. The Decision means that Member countries will co-operatively:

- select the chemicals to be investigated;
- collect effects and exposure information from government and public sources and encourage industry to provide information from their files;
- complete the agreed dossier for the Screening Information Data Set (SIDS) by testing; and
- make an initial assessment of the potential hazard of each chemical investigated.

When a full SIDS dossier on a chemical is available, an initial assessment of the information is undertaken and conclusions are drawn according to the potential risks posed by the chemical and recommendations are made on the need for further work. The conclusion might be, for example, that the chemical is of low potential risk and therefore currently of low priority for further work. If a potential risk to man and/or the environment is identified, various conclusions might be possible: limited exposure or current risk management measures in Member countries could make further action to manage the risk unnecessary at this time; it could be recommended that IPCS (International Programme on Chemical Safety) consider the chemical a candidate for an Environmental Health Criteria or similar document; and/or it could be recommended that risk management actions be considered at the national or, as appropriate, international level. In addition, the conclusion might be that further information is required to assess concerns identified in the SIDS process, and that post-SIDS testing is recommended on such chemicals.

In the policy bodies of OECD, Member countries discuss and agree on any follow-up actions on chemicals posing a potential risk, and indeed, discuss and confirm all conclusions and recommendations made on all chemicals which have been assessed in the SIDS programme.

When full SIDS dossiers and initial assessment reports are finalised, the results are made available world-wide through UN bodies such as IRPTC (UNEP's International Register of Potentially Toxic Chemicals) and IPCS, with whom close co-operation is maintained to this effect.

The chemical industry fully supports the OECD activities on HPV chemicals because this work avoids duplication of efforts among chemical companies to test chemicals to fulfil various national and regional requirements. This OECD activity is undertaken in close co-ordination with other national, regional and international existing chemicals programmes.

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\* This document was prepared by the OECD Secretariat based on the agreements reached in the OECD Existing Chemicals Programme up to June 1997

## ***Background and Rationale***

The investigation of the safety of the nearly 100,000 chemicals currently in commerce is a daunting global challenge that can only be met if approached in a systematic way. This enormous task has been undertaken by the OECD and is based on compilation, review and assessment of environmental health and safety data and exposure information on selected existing chemicals.

Many existing chemicals are international commodities. Various national governments and chemical companies have independently initiated activities to evaluate their safety, often using the guidance developed by the OECD. Such activities, however, are time and resource intensive and have led to the duplication of efforts on (groups of) chemicals. In order to tackle this problem, Member countries decided through a Council Decision-Recommendation in 1987 [C(87)90(Final)] to undertake a Systematic Investigation of Existing Chemicals. They agreed to establish or strengthen national programmes to investigate existing chemicals, in order to identify those which pose risks that need to be managed and/or controlled. In 1990, it was recommended in a further Council Decision (on the Co-operative Investigation and Risk Reduction of Existing Chemicals) that Member countries work together and "share the burden" of investigating the potential risks from priority chemicals of mutual concern. By sharing the burden in this manner, and by working towards internationally agreed objectives, governments could avoid wasting resources by duplicative efforts. Industry also benefits by avoiding duplication of information gathering or testing to fulfil various national and regional requirements and international commitments.

In order to share the burden of investigation, each Member country carries out a specific part of the total work and makes the information it has collected or generated available to other Member countries. Chemical industries in Member countries play a significant role in the conduct of this co-operative work. The Business and Industry Advisory Committee to OECD (BIAC) and national chemical industry associations promote the collection of information and help ensure that tests which need to be conducted are undertaken in a timely manner. The work is carried out in collaboration with the International Programme on Chemical Safety (IPCS) and the International Register of Potentially Toxic Chemicals (IRPTC, now called UNEP Chemicals).

This co-operative OECD work leads to considerable benefits for many parties:

- Environmental protection and human health will be improved as existing chemicals are investigated more effectively.
- The financial costs of testing will be substantially reduced as a result of increased co-operation and sharing the burden in testing.
- The mutual understanding of national procedures for initial assessment of chemicals will be increased, leading to eventual harmonization of these procedures.
- The use of animals in testing will be reduced, as much duplicative testing will be avoided.

## ***Objectives***

Since 1988, OECD existing chemicals activities have centred primarily on the investigation high production volume (HPV) chemicals, based on the assumption that production volume is an indicator of potential occupational, consumer and environmental exposure.

- The first objective of this co-operative work is to ensure that the basic information necessary to undertake a first evaluation of potential hazards associated with HPV chemicals is either available or generated.
- A second objective is to undertake an initial assessment of this information and to draw conclusions on the potential risk of the chemicals and make recommendations related to the need for further work.
- Finally, when complete data sets and risk assessments are available, Member countries may decide to develop common, consistent or harmonized risk management actions for those HPV chemicals which have been found to be of concern to man or the environment.

## ***The OECD List of High Production Volume Chemicals***

The OECD List of HPV Chemicals is compiled on the basis of submissions by Member countries to the OECD Secretariat. These submissions contain industrial chemicals for which a Chemical Abstracts Service (CAS) Registry Number had been assigned. For the first OECD List in 1990, eighteen Member countries (including all major chemical producing countries) provided national inventories of HPV chemicals produced in or imported into their countries. These inventories were merged into the OECD List, which included all chemicals reported to be produced or imported in excess of 10,000 tonnes per year in any one Member country or in excess of 1,000 tonnes per year in two or more countries.

The List has been modified a couple of times. The 1997 OECD HPV List is currently being compiled by combining the European Union's HPV list (i.e. Annex I to EC Regulation 793/93) and the updated national HPV submissions from non-EU OECD Member countries. It was agreed at the 26th Joint Meeting (i.e. the Joint Meeting of the Chemicals Group and Management Committee of the Special Programme on the Control of Chemicals) that the definition of the HPV chemicals be modified to "all chemicals reported to be produced or imported at levels greater than 1,000 tonnes per year in at least one Member country as of the 1997 List. It is expected to contain about 4,000 entries.

Any chemical on the 1997 OECD List of HPV Chemicals can be sponsored by Member countries as their share of the co-operative work on HPV chemicals. Member countries can select either chemicals for which limited data are available and for which development of SIDS data is needed (i.e. "data poor" chemicals), or chemicals for which full SIDS information is available and for which an initial assessment can be carried out without delay (i.e. "data rich" chemicals). In this way the work undertaken in the EU Member States in compliance with the EC Regulation forms their contribution to the OECD programme.

### ***Priority Setting***

The priority setting procedure has evolved since the OECD programme began. At the beginning, Member countries surveyed the 1990 List and by consulting national and/or international databases gathered data that were readily available for the individual chemicals. The annotated List was then reviewed at meetings of experts from Member countries, other international organisations and industry, where it was decided that those substances for which little or no information was available should have highest priority for further work in the phases of the SIDS project. As a result of these deliberations, a "working list" of 648 chemicals was developed in 1992, from which Member countries selected chemicals for sponsorship.

As of 1993, selection was no longer limited to the "working list". This change was made in order to allow those Member countries with small chemical industries to participate and to follow the evolution of national and regional existing chemicals programmes - some of which are currently aimed less at filling data gaps and more at assessing chemicals of concern for which a great deal of data are available, in order to recommend further action as appropriate. The OECD List of HPV Chemicals serves as the overall priority list from which chemicals are selected for SIDS testing and/or assessment. This gives Member countries greater flexibility in the programme and facilitates the participation of industry. Chemicals for which SIDS data gap are probable will be identified by searching main databases and these will be marked in the 1997 OECD List of HPV Chemicals for the information of Member countries wishing to sponsor "data poor" chemicals.

### ***Selection of Chemicals***

In order to share the burden, chemicals are selected by Member countries in batches of approximately 50 for every "phase" of the programme. In consultation with their chemical industries, they identify chemicals for which, on a voluntary basis, they will act as a Sponsor country in the HPV programme. The overall number of chemicals which any Member country or group of Member countries (through, for example, the EU programme) sponsors should, as a minimum, be proportional to its financial contribution to the OECD Chemicals Programme, which in turn is proportional to its (combined) Gross National Product.

### ***The Screening Information Data Set (SIDS)***

The objective of this OECD activity is to undertake an initial screening of the potential risks of HPV chemicals to man and/or the environment. A prerequisite for this generic approach was the identification of the necessary elements, or data set, on which to base an informed judgement as to the potential hazards of the chemicals. The data elements needed for "screening" HPV chemicals were brought together as the Screening Information Data Set, or SIDS, which comprises

characterisation and effects data similar to the Minimum Pre-marketing set of Data (MPD) for new chemicals (the OECD Council Decision in 1982 [C(82)196(Final)]), as well as elements of exposure information (see Section 2.2). The SIDS is regarded as the minimum information needed to assess an HPV chemical to determine whether any further work should be carried out or not. However, all available data are used to make the assessment. In practice, and especially following the change in scope of the chemicals covered, the available data often goes far beyond SIDS.

### ***Responsibilities of a Sponsor Country***

Each Sponsor country nominates a SIDS Contact Point who organises the actual work and is available for communication (see Annex 6 to this Manual). The responsibilities of a Sponsor country, again in collaboration with its industry, include:

- preparing and managing the collection of effects and exposure data (if necessary, undertaking a further literature search);
- identifying a lead organisation, usually a chemical company, for each chemical;
- reviewing the data received, assessing their quality, preparing a SIDS Dossier and developing, as appropriate, a SIDS Testing Plan for generating further information by testing;
- providing the information on SIDS testing/no testing for the Secretariat;
- organising and supervising any agreed SIDS testing;
- assisting other national SIDS Contact Points by forwarding exposure information or other requested data on their chemicals;
- making an evaluation of the full SIDS Dossier and preparing a SIDS Initial Assessment Report (SIAR), including proposals for conclusions and recommendations on any follow-up actions to be undertaken on the chemical;
- circulating the SIAR to other Member countries and presenting it at a SIDS Initial Assessment Meeting (SIAM); and
- finalising the SIAR for publication, taking into account the comments provided and discussions at a SIAM.

Each Member country is responsible for generating and making available SIDS data for those priority HPV chemicals for which it is the Sponsor country. In return, it will benefit from receiving similar data on the other priority HPV chemicals from other Member countries and from the fact that the need for duplicate testing will be eliminated.

### ***Data Collection, SIDS Dossiers and Testing Plans***

After selection of chemicals by Sponsor countries, the first activity involves collection of information on the chemicals. In addition to readily available data, industry is also requested to provide Sponsor countries with data and full copies of studies which are in their files and have not so far been published in the open literature.

To assist Sponsor countries in the collection of data in a standardised manner, the OECD in co-operation with the European Commission has developed a computer format, which can be used by responders when providing information. Not only all information required by the SIDS, but also further information on existing chemicals required within the framework of the EU programme, can be accommodated in the system. Diskettes on which the data elements for the Harmonized Electronic Data Set (HEDSET) may be entered, together with explanatory documents on recording information, are available from the Secretariat, the European Commission and SIDS Contact Points (see Section 2.3).

As additional information, beyond SIDS elements, could be helpful to the Sponsor country in formulating its plan for SIDS testing, HEDSET includes a wider range of data elements than those required in the SIDS. Information holders are therefore encouraged to provide information for as many of the data elements on the diskette as possible.

Although use of the HEDSET diskette is strongly encouraged, either the paper form, the "Revised OECD HPV Form 1" (see Section 2.4), in Word 6.0 or its diskette equivalent, are acceptable alternatives. The empty form is available from SIDS Contact Points or the OECD Secretariat.

At this stage, information on exposure of the chemical should also be collected. Sponsor countries of the chemicals collect detailed information, whereas other countries also collect easily-available information and transmit it to relevant Sponsor countries (see Section 2.2 and 2.5).

When no information is available for a given data element, calculation or estimates derived from Quantitative Structure Activity Relationships (QSARs) can sometimes be provided (e.g. for physical-chemical properties or aquatic toxicity), but an indication of the quality of the methods used should be given.

For any SIDS element on effects or characterisation for which no data are available or the data are not considered adequate, testing will in principle be carried out.

Any testing to complete the SIDS should be conducted according to the OECD Test Guidelines and the Principles of Good Laboratory Practice (GLP), in order to ensure that generated data are mutually acceptable among Member countries and that tests carried out in accordance with the OECD Council Decision on the Mutual Acceptance of Data [C(81)30(Final)] need not be repeated.

The quality of the collected data is of great importance. In order to harmonize its evaluation and to assist Sponsor countries in preparing the SIDS Dossiers and SIDS Testing Plans for their chosen chemicals, the OECD has prepared guidance for evaluating and documenting the quality of data including a SIDS Guide which addresses details for each SIDS element (see Chapter 3). A Model Dossier has also been prepared to indicate what kind of data should be included, how the data should be expressed, etc. (see Annex 2 to this manual).

### ***SIDS Review***

Up to 1993, the SIDS Dossiers and SIDS Testing Plans had been forwarded by the Sponsor country to all SIDS Contact Points, so that the experts from each OECD country and those from non-Member countries nominated by IPCS could study the proposals made by the Sponsor country. The proposals were then scrutinised at a meeting of experts of Member countries (SIDS Review Meeting) in order to confirm the adequacy of information and reach agreement on the SIDS Testing Plan.

Beginning with phase 4, this SIDS Review was undertaken via a written procedure by sending the SIDS Dossiers and SIDS Testing Plans to all SIDS Contact Points. However, it was agreed in November 1996 to simplify the procedures by circulating a statement regarding testing needs with relevant information. This is aimed at reducing work for countries but still informing the Secretariat and all Member countries of progress and decisions regarding data quality and testing needs taken by Sponsor countries (see Section 3.1 for details).

The Secretariat collates the information provided by Sponsor countries and circulates it to all SIDS Contact Points. Any comments are provided to Sponsor countries through SIDS Contact Points within 2 months. If opposing views exist, they will be discussed bilaterally between the individual Member country providing comments and the Sponsor country. Where no consensus can still be reached, discussion and resolution should, in principle, be handled by the Steering Group on Existing Chemicals, a sub-group of the Joint Meeting. Sponsor countries can request preliminary discussion of SIDS Dossiers and Testing Plans at a SIDS Initial Assessment Meeting (SIAM).

Following these SIDS Review procedures, the outcome concerning the data needs for SIDS end-points is one of the following:

- existing data are adequate; no testing is needed;
- existing data are not adequate; agreed testing will be carried out; or
- existing data are not adequate, but there is agreed (written) scientific justification for not requiring testing.

### ***Initial Assessment of Full SIDS Chemicals***

When the Sponsor country has obtained all the data elements of the SIDS for the sponsored chemical (a Full SIDS Chemical), it will prepare the SIDS Initial Assessment Report (SIAR) to accompany the full SIDS Dossier on the chemical and make an evaluation including conclusions on the potential risk and recommendations for further action, if appropriate.

Five provisional guidance documents for Sponsor countries to use in carrying out initial assessments and preparing their recommendations have been developed and reviewed by Member countries, taking into account experience obtained at SIAMs. These documents are included in Chapter 4:

- Provisional Guidance for the Outline of the SIDS Initial Assessment Report
- Provisional Guidance for the Initial Assessment of Environmental Exposure
- Provisional Guidance for the Initial Assessment of Occupational and Consumer Exposure
- Provisional Guidance for the Initial Assessment of Aquatic Effects
- Provisional Guidance for the Initial Assessment of Health Effects

Models used for exposure estimation have been developed based on the results of various OECD workshops and have been distributed to SIDS Contact Points (see Sections 4.3 and 4.4).

### ***Peer Review***

The SIDS Dossiers and Testing Plans as well as the SIDS Initial Assessment Reports (SIARs) are subject to extensive peer review in two stages. As discussed above, in the first stage, a statement of SIDS-testing/no testing together with relevant information is circulated to SIDS Contact Points who review and comment on the adequacy of the Sponsor country's decision. A two-month period is allowed for this review. Sponsor countries receive comments via SIDS Contact Points and complement their data and/or adjust their Testing Plans as appropriate.

In the second stage, the SIARs, which include evaluations, conclusions and recommendations, are circulated, together with the updated SIDS Dossier, to SIDS Contact Points in a timely manner prior to the SIDS Initial Assessment Meeting (SIAM). Once again, experts in countries are consulted and comments prepared for discussion at the SIAM. In some cases, initial comments are relayed to the Sponsor country prior to the SIAM, so a revised SIAR can be prepared and circulated, if appropriate. Three months are allowed for this process. At the SIAM itself, the SIARs are discussed and consensus reached on the initial assessment and the conclusions and recommendations for each chemical, resulting in an internationally agreed assessment.

Participants in the SIAM include:

- representatives of the Sponsor countries;
- representatives from other Member countries and the European Commission;
- experts from non-Member countries nominated by IPCS;
- secretariat staff from OECD, IPCS and IRPTC;
- experts nominated by OECD's Business and Industry Advisory Committee (BIAC) and Trade Union Advisory Committee (TUAC); and
- representatives of companies which produce the chemical (for that part of the discussions which concerns their chemical).

### ***Outcome and public availability***

For each chemical, the end product of the work, in the framework of the OECD Existing Chemicals activities, should be that all data elements of the SIDS (Full SIDS) are available, their adequacy has been peer reviewed and an initial assessment report prepared. This information will have been evaluated, and conclusions on the potential risk posed by the chemical and recommendations for further actions, if any, agreed among Member countries.

The conclusions and recommendations might state, for example, that the chemical is of low potential risk and therefore currently of low priority for further work. If a potential risk to man and/or the environment is identified, various conclusions might be possible: limited exposure or current risk management measures in Member countries could make further action to manage the risk unnecessary at this time; it could be recommended that IPCS consider the chemical a candidate for a Health and Safety Guide or an Environmental Health Criteria document; and/or it could be recommended that risk management actions be considered at the national or, as appropriate, international level. In addition, the conclusion

might be that further information is required assess concerns identified in the SIDS process, and that post-SIDS testing is recommended on such chemicals.

The conclusions and recommendations on the chemicals agreed at a SIAM are reported to the Steering Group on Existing Chemicals and confirmed. They are subsequently transmitted to the Joint Meeting to be endorsed.

Sponsor countries finalise the SIAR taking into account the comments provided by other countries and the discussion at a SIAM, and submit it to the OECD Secretariat together with the SIDS Initial Assessment Profile and the Full SIDS Dossier or the finalised data in the HEDSET. In addition, Sponsor countries are expected to make test reports supporting these data publicly available, wherever possible.

The Secretariat transfers the submitted SIAR and other information to IRPTC for inclusion in their database and publication as a contribution to the International Programme on the Sound Management of Chemicals (IOMC). These are also made available on Internet. In this way, all information resulting from the OECD SIDS Programme will be available world-wide.

### ***Post-SIDS Activities***

Where a chemical has been reviewed at the SIAM and it has been recommended that further information is required to assess identified concerns, any follow-up testing or information gathering is regarded as post-SIDS work. The SIAM will give an indication of what data need to be collected, generated and/or analysed, and the priority relative to other chemicals for which post-SIDS work is envisaged.

Although a Member country will monitor progress and oversee development of this additional work, the overall responsibility for initiating and undertaking any work rests with industry. Industry has the most knowledge about their chemicals, and is in the best position to negotiate ways and means of sharing the burden of the administrative and operational costs involved.

The Member country, in collaboration with industry, supervises the work in order to promote the establishment by producer and user industries of "consortia" to undertake the work, to monitor that any necessary testing is conducted appropriately under the suggested schedule, and to circulate the final report of the work to SIDS Contact Points. Non-Member countries are encouraged to participate in the programme and share the burden.

When all the additional information has been collected or generated and analysed, the chemical will be discussed at a Post-SIDS Assessment Meeting, which will have a similar format and participation as the SIAM. The results of post-SIDS work and/or a revised SIAR will be provided to IRPTC and IPCS and be publicly available.

Some chemicals for which SIAM draws the conclusion that the initial assessment has shown them to pose a potential risk to man and/or the environment may not require any further work in the SIDS context and might be considered candidates for follow-up in IPCS, in order to build on the information provided in the SIAR and to make it more useful in a global context.

Some chemicals of concern may be considered by SIAM to have a limited potential for exposure and/or to be adequately managed in OECD countries. Recommendations might be made to the effect that BIAC will continue to monitor risk management activities by industry for these chemicals.

Certain chemicals of concern might be considered by SIAM to require risk management action, either nationally or internationally. Further consideration of proposed risk management actions will be discussed at the Advisory Group on Risk Management, another sub-group of the Joint Meeting.

### ***Overview of the SIDS process including Post-SIDS work***

A synopsis of the stages involved in the OECD work on SIDS is presented below (also see the flowchart in Annex to this Chapter):

- 1) development and maintenance of an OECD List of HPV chemicals;

- 2) selection of chemicals from the List by Sponsor countries;
- 3) collection of data;
- 4) review of the quality of data, preparation of SIDS Dossiers and SIDS Testing Plans;
- 5) circulation of the information on SIDS-testing/no testing to all SIDS Contact Points;
- 6) agreement on SIDS Testing Plans through the SIDS Review (by written procedure);
- 7) SIDS Testing and/or collection of information, as appropriate;
- 8) preparation of a SIDS Initial Assessment Report by the Sponsor country with conclusions on potential risk and recommendations on further work to be undertaken;
- 9) co-operative initial assessment and agreement on conclusions and recommendations at the SIAM and confirmation at the Steering Group on Existing Chemicals and the Joint Meeting;
- 10) if necessary, further testing and/or data analysis (post-SIDS work) and post-SIDS assessment; recommendation as candidate for development of an IPCS document; or recommendation as a candidate for national or international risk management activities.

### ***Co-operation with International Organisations***

In the SIDS programme, it has been demonstrated that Member countries can successfully co-operate in gathering data, testing and assessing existing chemicals. It should be noted that in January 1991, after consideration by Environment Ministers of the results from the first phase of SIDS work, Member countries made a formal commitment, in the form of the OECD Council Act on Co-operative Investigation and Risk Reduction of Existing Chemicals [C(90)163(Final)], that they would co-operate in the systematic investigation and assessment of existing chemicals. In this Council Act, particular attention is paid to co-operation with international organisations.

In the Council Act, it was decided that Member countries shall make information obtained from the co-operative investigation of existing chemicals publicly available via IRPTC, while respecting legitimate claims for protection of confidential data. IRPTC has agreed that it will not only work as an archive for the data collected or generated in the SIDS project, but also disseminate data through its databases. Therefore, SIDS Initial Assessment Reports and all information summarised in the SIDS dossiers or in the HEDSET are transmitted to IRPTC and entered in the IRPTC database. Responding to the request made by UNCED in Agenda 21 to expand and accelerate the international assessment of chemical risks, IRPTC is now issuing a new series of documents including the OECD initial assessments of HPV chemicals, both in paper form and on Internet. It is anticipated that in the near future the data collected on HEDSET and the assessment report itself will be able to be transferred directly through electronic means to IRPTC, and from IRPTC to users throughout the world.

IPCS was invited, through the Council Act, to use the results of the investigations of existing chemicals by OECD Member countries in preparing its assessments of the health and environmental impacts of existing chemicals. Information collected will be used in the preparation of Environmental Health Criteria or other documents by the IPCS on specific chemicals of concern. (*not modified*)

### ***References***

- OECD Council Decision on the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final)], May 1981.
- OECD Council Decision on the Systematic Investigation of Existing Chemicals [C(87)90(Final)], July 1987.
- OECD Council Decision-Recommendation on the Co-operative Investigation and Risk Reduction of Existing Chemicals [C(90)163(Final)], January 1991 (see Annex 1 to this manual).
- Council Regulation (EEC) No. 793/93 on the Evaluation and Control of the Risks of Existing Substances, European Communities, 23 March 1993

The following articles will be of interest:



- Brydon, James E., Morgenroth III, Victor H., Smith, Alan M. and Visser, Rob (1990); OECD's Work on Investigation of High Production Volume Chemicals, International Environment Reporter, June 1990, 263-270.
- Smith, Alan M., Arai, Shin-ichi, Tanaka, Katsutoshi and Visser, Rob (1993); Review of the SIDS Project of the OECD Existing Chemicals Programme, International Environment Reporter, November 3, 1993.
- Turnheim, Dian (1994); Evaluating Chemical Risks, OECD Observer, 189, August/September 1994, 12-15.

